114 (4)

Supreme Court, U.S.
FILED
DEC 10 2008
OFFICE OF THE CLERK

No. 08-624

IN THE

Supreme Court of the United States

FOREST LABORATORIES, INC.,
FOREST LABORATORIES HOLDINGS, LTD.,
AND H. LUNDBECK A/S,
Petitioners,

v.

CARACO PHARMACEUTICAL LABORATORIES, LTD.,
Respondent.

On Petition for Writ of Certiorari To the United States Court of Appeals For the Federal Circuit

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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Date: December 10, 2008

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QUESTION PRESENTED

Whether a generic drug company possesses Article III standing to sue for a declaratory judgment that it has not infringed a patent relating to an FDA-approved drug, where the patentee has granted it an irrevocable covenant not to sue for infringement.

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BRIEF OF WASHINGTON LEGAL FOUNDATION AS AMICUS CURIAE IN SUPPORT OF PETITIONERS

INTERESTS OF *AMICUS CURIAE*

The Washington Legal Foundation (WLF) is a non-profit public interest law and policy center with supporters in all 50 States.[1] WLF devotes a substantial portion of its resources to defending free-enterprise, individual rights, and a limited and accountable government.

WLF believes strongly that maintenance of a limited government requires courts to respect limitations on their jurisdiction and to avoid reaching out to adjudicate matters not involving a justiciable case or controversy. WLF has regularly participated in federal court proceedings in which the scope of the judicial power is at issue. *See, e.g., Friends of Earth v. Laidlaw Environmental Services (TOC),* 528 U.S. 167 (2000); *Steel Co. v. Citizens for a Better Env't,* 523 U.S. 83 (1998). WLF filed a brief in this case in the Federal Circuit, in support of the petition for panel rehearing and rehearing *en banc*.

WLF is concerned that the Federal Circuit's decision, if allowed to stand, would expand federal court jurisdiction w ell beyond the limitations imposed by

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[1] Pursuant to Supreme Court Rule 37.6, WLF states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than WLF and its counsel, made a monetary contribution intended to fund the preparation and submission of this brief. More than ten days prior to the due date, counsel for WLF provided counsel for Respondent with notice of its intent to file this brief.

Article III of the Constitution, which limits jurisdiction to "Cases" or "Controversies." WLF does not believe that federal courts should be in the business of rendering advisory opinions of the sort Respondent Caraco Pharmaceutical Laboratories, Ltd. ("Caraco") is seeking in this case. In the absence of any case or controversy, Caraco's appropriate recourse is to take its case to Congress and to request revision of the rules governing the grant of a 180-day exclusivity period for the first filer of an ANDA – not to complain to a court about the unfairness of those rules.

WLF has no direct interest – financial or otherwise – in the outcome of this case. It is filing its brief for the sole purpose of urging the Court to establish firm rules designed to ensure that federal courts operate exclusively within the confines of their Article III jurisdiction. WLF is filing its brief with the consent of all parties; letters of consent have been lodged with the Court.

STATEMENT OF THE CASE

Petitioners Forest Laboratories, Inc., *et al.* (collectively, "Forest"), developed (and for a number of years have been marketing) Lexapro®, a drug approved by the Food and Drug Administration (FDA) for treatment of depression and generalized anxiety disorder. Prior to initiation of this lawsuit, Forest owned two patents that covered Lexapro or its use, and it listed those patents in FDA's Orange Book.

Because of Lexapro's commercial success, numerous generic drug companies are interested in marketing a generic form of Lexapro. But federal law

prohibits a generic drug company from doing so until such time as FDA approves the company's Abbreviated New Drug Application (ANDA) for its generic version of the drug. It is the absence of an approved ANDA, not Forest's patents, that ultimately is preventing Caraco from marketing a generic version of Lexapro.

In seeking to promote the Nation's health care delivery system, Congress has recognized two important goals that are in considerable tension with one another. On the one hand, Congress seeks to provide an economic incentive for new product development by granting pharmaceutical companies that gamble the substantial sums necessary for the development of new therapies the opportunity to reap substantial rewards in those few instances in which their research and development bear fruit. It does so by affording pioneering drug manufacturers a substantial period of exclusivity, during which potential competitors are not permitted to market the same product. On the other hand, once that appropriate period of exclusivity has expired, Congress has determined that consumers are well served by government policies that encourage other companies to market generic versions of the new drug, thereby ensuring the competition necessary to produce lower prices.

There is an inherent tension between these two goals – rewarding research and development while lowering the cost of drugs through competition. Congress attempted to strike a balance between those competing interests when, in 1984, it adopted the Drug Price Competition and Patent Term Restoration Act, commonly referred to as the Hatch-Waxman Act. *See* Pub. L. 98-417, 98 Stat. 1585 (1984), codified at 21

U.S.C. § 355 and 35 U.S.C. §§ 156 and 271(e). The Act benefitted generic manufacturers by creating the ANDA procedure, which greatly streamlined the process by which generic manufacturers can receive FDA approval to market generic copies of pioneer drugs. 21 U.S.C. § 355(j). The Act benefitted pioneering manufacturers by granting patent-term extensions under certain circumstances. 35 U.S.C. §§ 156 & 21 U.S.C. § 355a(c)(2).

The Act also included a provision designed to encourage challenges to potentially invalid drug patents – it provided rewards to the first generic drug manufacturer to take on the burden of challenging a drug patent. The Act provided that, subject to certain limitations, the first ANDA filer was entitled to a 180-day exclusivity period following the launch of its product pursuant to an approved ANDA, during which no other generic company's ANDA would be approved. 21 U.S.C. § 355(j)(5)(B)(iv).

The Act also set forth procedures for resolving patent disputes between pioneering and generic manufacturers. Those procedures are set forth in § 505(j) of the Federal Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. § 355(j). The FDCA provides that FDA is to maintain a list of FDA-approved drugs and to include on that list (known as the "Orange Book") any patent information respecting those drugs. 21 U.S.C. § 355(j)(7)(A).[2] If a generic manufacturer seeks to

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[2] Supplying such patent information to FDA is not optional. Any pioneering drug company that applies to FDA to market a new drug *must* include in its application detailed information regarding all patents that claim the drug or a method of using the drug. 21

market a generic version of an approved drug for which a patent is claimed in the Orange Book (and wants to do so before the expiration of a listed patent), the manufacturer must include in its ANDA a certification "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." 21 U.S.C. § 355(j)(2)(A)(vii)(IV).[3] Congress has decreed that the filing of a Paragraph IV certification injures a patent holder by infringing his property rights in the patent, and has authorized patent holders to file an infringement suit against the Paragraph IV filer. 35 U.S.C. §§ 271(e)(2)(A) & 281. The Act also permits the filer of a Paragraph IV certification, under certain circumstances, to file a civil action for a declaratory judgment of noninfringement and/or invalidity. 21 U.S.C. § 355(j)(5)(C).

Caraco notified Forest of its ANDA filing in May 2006, many years after the first ANDA for generic Lexapro was filed by Ivax Pharmaceuticals, Inc. Ivax's ANDA included Paragraph IV certifications with respect to the two patents listed in the Orange Book for Lexapro (the '712 patent and the '941 patent). In subsequent patent infringement litigation initiated by Forest with respect to the '712 patent, the federal courts upheld the patent and held that it was infringed by Ivax's filing. *Forest Labs., Inc. v. Ivax Pharms., Inc.*, 501 F.3d 1263 (Fed. Cir. 2007). Forest did not sue Ivax over the '941 patent. Because the '712 patent does not expire until

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U.S.C. §§ 355(b)(1) & (2), 355(c)(2).

[3] Such a certification is often referred to as a "Paragraph IV certification."

2012, FDA will not approve the sale of a generic version of Lexapro until after that date – unless another generic manufacturer successfully challenges the '712 patent in court.

As noted above, by virtue of its status as the first Paragraph IV filer with respect to both the '712 patent and the '941 patent, Ivax is entitled to a 180-day exclusivity period during which the numerous ANDAs filed by other generic drug companies will not be approved. 21 U.S.C. § 355(j)(5)(B)(iv). In all likelihood, the 180-day period will be deemed to commence on the day that Ivax begins selling its generic drug (presumably in 2012, when the '712 patent expires). Caraco filed this suit in hopes that it can trigger an earlier start to the 180-day exclusivity period and thereby accelerate the launch of its own generic version of the drug.

Caraco's ANDA for Lexapro, filed in May 2006, included a Paragraph IV certification for both the '712 patent and the '941 patent. Forest responded by suing Caraco for infringement of the '712 patent; that suit is scheduled for trial in April 2009. Forest did not sue Caraco for infringement of the '941 patent, nor does Caraco allege that Forest ever threatened such a suit.

Caraco nonetheless filed this declaratory judgment action against Forest, seeking a declaration that the drug described in its ANDA did not infringe Forest's '941 patent. Forest thereafter granted Caraco an irrevocable covenant not to sue for infringement of

the '941 patent. Pet. App. 19a.[4] Based on that covenant, the district court granted Forest's motion to dismiss the case, finding that it lacked Article III jurisdiction in light of the absence of any controversy between the parties regarding Caraco's noninfringement of the '941 patent. *Id.* 49a-79a.

Splitting 2-1, a Federal Circuit panel reversed the district court's jurisdictional ruling and remanded the case. *Id.* 1a-43a. The majority held that Caraco's declaratory judgment action "present[ed] a justiciable Article III controversy," based on its determinations that Caraco possessed standing to sue, that the controversy was ripe for review, and that the granting of a covenant not to sue did not render the case moot. *Id.* 23a.

In its analysis of standing, the appeals court held that Caraco is suffering injury-in-fact because, the court concluded, the listing of the '941 patent in the Orange Book was an obstacle to Caraco's effort to win FDA approval of its ANDA. *Id.* 24a. The court explained that but for the '941 patent listing, Caraco would be permitted to market its drug 180 days following expiration of the '712 patent (or 180 days after a judgment striking down the '712 patent, which ever

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[4] In its filings in the courts below, Caraco repeatedly observed that Forest did not explicitly concede that the Caraco ANDA did not infringe the '941 patent. WLF fails to understand the relevance of that observation, particularly given Caraco's failure to challenge the validity of the '941 patent. For all practical purposes, a patentee's covenant that it will not sue X for infringement of its patent is equivalent to a statement by the patentee that X has not infringed its patent.

comes first), rather than being forced to wait until 180 days after Ivax voluntarily decides to begin marketing its drug -- and that that impediment to marketing constituted the requisite injury-in-fact. *Id.* 24a-25a.[5] The court held that Caraco's injury was "fairly traceable" to Forest's complained-of conduct in that Forest's Orange Book listings were a "but-for" cause of the injury: but for those listings, Caraco's ANDA would readily be approved. *Id.* 26a. The court also held that Caraco's injury is redressible by this lawsuit: granting a declaratory judgment would "clear the path" to FDA approval of Caraco's ANDA, because at that point the only obstacles to approval would be a Caraco victory in its pending judicial challenge to the '712 patent followed by the elapse of 180 days. *Id.* 28a.

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[5] Caraco argued in the appeals court that by virtue of Ivax's loss of the patent infringement action suit filed by Forest, Ivax has forfeited its 180-day exclusivity period with respect to the '712 patent, and thus that if Caraco wins this suit it will be permitted to begin marketing on the very day that the '712 patent expires (or the day that it is held invalid). However, the Federal Circuit has repeatedly made clear that it rejects that argument. Rather, the Federal Circuit has stated, a generic drug manufacturer's 180-day exclusivity period with respect to a Paragraph IV certification remains in effect even if its challenge to the listed patent is rejected. *See, e.g., id.* at 14a ("[B]ecause Ivax was the first Paragraph IV ANDA filer with respect to both the '712 and '941 patents, a subsequent Paragraph IV ANDA filer can only activate Ivax's exclusivity period via the court-judgment trigger by obtaining a judgment that both the '712 and '941 patents are invalid or not infringed."). In other words, even if Caraco manages to activate the court-judgment trigger with respect to both patents, it must still wait 180 days before it can begin marketing its drug. In the absence of a cross-petition from Caraco on this issue, the Federal Circuit's interpretation of the rules governing the 180-day exclusivity period are controlling.

The appeals court also held that Caraco's declaratory judgment action was ripe for review, *id.* 31a-34a, and that it had not been rendered moot by Forest's grant of an irrevocable covenant not to sue Caraco for infringement of the '941 patent. *Id.* 34a-36a. The court said that Forest's covenant did not eliminate Caraco's injury: the potential delay in FDA approval of its ANDA caused by the existence of Forest's Orange Book listings.

REASONS FOR GRANTING THE PETITION

The petition raises issues of exceptional importance. By limiting the federal judicial power to the resolution of actual "Cases" and "Controversies," Article III of the Constitution plays an important role in maintaining a balanced allocation of power among the three branches of the federal government. The case-or-controversy requirement ensures that the federal courts limit the exercise of their powers to those occasions on which parties with adverse legal interests are engaged in a concrete and substantial dispute, and do not render decrees that opine on hypothetical facts or adjudicate "disputes" that are not actually disputed by the parties. Yet, the Federal Circuit has now determined that it possesses jurisdiction to issue just such decrees in a category of patent cases that affects a large number of extremely valuable drug patents. Its stated rationale for doing so is a desire to ensure that generic drugs can be more easily marketed – thereby potentially reducing consumers' prescription drug costs.

Review is urgently needed to ensure that the Federal Circuit, along with all other federal courts, confine their exercise of jurisdiction to cases and controversies falling within their Article III powers.

The Federal Circuit determined that a generic drug company has standing to file an action seeking a declaratory judgment that its proposed marketing plans do not infringe an existing patent, even though the patentee never gave the company any indication that it intended to sue for infringement and, indeed, ultimately provided the company with an irrevocable covenant that it would *never* sue for infringement. When there is not, nor has there ever been, a disagreement between two parties regarding the scope of a patent, it defies all understanding to suggest that there exists a justiciable controversy regarding the patent. The mere fact that if a judgment is rendered, one party may gain an advantage in some other proceeding – in this instance, Caraco's application for ANDA approval – does not alter the fact that Article III deprives federal courts of authority to exercise jurisdiction over matters that are not genuinely in dispute. It is up to Congress – not the Federal Circuit – to determine if changes are warranted in FDA drug-approval rules for the purpose of further streamlining the ANDA process and thereby bringing about further reductions in retail drug prices.

The Federal Circuit shrugged off Forest's objections to having to defend a lawsuit in which no issues are genuinely in dispute, by stating that Forest could avoid the costs of litigation it if would merely "submit to a consent decree that the drug described in Caraco's ANDA does not infringe the '941 patent." Pet. App. 28a n.11. But the consent of the parties does not relieve federal courts of their independent obligation to ensure that they are operating within the constitutionally prescribed limits to their powers. *Arizonans for Official English v. Arizona*, 520 U.S. 43, 73 (1997). While some patentees may agree to a consent

judgment rather than going to the expense of contesting jurisdiction in a suit seeking a declaration of noninfringement that no one disputes, that does not excuse a federal court's decision to exercise jurisdiction in a matter so clearly outside its Article III powers.

The appeals court's determination that Caraco has suffered injury-in-fact sufficient to establish standing cannot withstand analysis. In past instances in which the Court has upheld jurisdiction over an action seeking a declaratory judgment that a patent is either invalid or not infringed, it has done so based on findings that the mere existence of the patent has in some way harmed the plaintiff. Either the patentee has created reasonable apprehension that the plaintiff will be sued for infringement, or the patent causes the plaintiff to forebear from activity that it would engage in but for the likelihood that doing so would lead to a potentially ruinous patent infringement suit. *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 S. Ct. 764 (2007).

In this case, Caraco does not allege that it has been harmed by the existence of the '941 patent or even that the '941 patent is invalid. Rather, Caraco asserts that it has been injured due to potential delays by FDA in approving its ANDA to market generic Lexapro, and that those potential delays are greater than they might otherwise have been had Forest not caused the '941 patent to be listed in the Orange Book. Given that Caraco does not allege that it has been injured by the existence of the '941 patent, it lacks standing to bring a

declaratory judgment action with respect to the patent.[6]

There is no reason to delay review of the issue to allow it to percolate in the federal appellate courts. Because all patent cases come through the Federal Circuit, all such cases will be decided under the overly expansive understanding of Article III jurisdiction adopted in this case. Moreover, as the appeals court recognized, Pet. App. 10a n.4, its analysis of Article III jurisdictional limits applies both to cases (as here) where 180-day exclusivity issues are governed by the pre-2003 statutory scheme and to cases in which such issues are governed by the new statutory scheme adopted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003)("MMA"). *See* 21 U.S.C. § 355(j)(5)(D). Accordingly, unless review is granted in this case, the Federal Circuit is likely to continue to exercise jurisdiction in patent cases well beyond the scope of its Article III authority.

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[6] Caraco's alleged injury would most likely be sufficient to establish standing to sue FDA for its decision to list the '941 patent in the Orange Book. But that is not the cause of action that Caraco has filed. Moreover, the Federal Circuit has made clear that federal law does not provide a cause of action against either FDA or patentees for improper Orange Book listings. *See, e.g., Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001), *cert. denied*, 537 U.S. 941 (2002).

I. REVIEW IS WARRANTED TO ENSURE THAT THE FEDERAL CIRCUIT CONFINES ITS EXERCISE OF JURISDICTION TO CASES AND CONTROVERSIES FALLING WITHIN ITS ARTICLE III POWERS

Caraco seeks a declaratory judgment that it has not infringed the '941 patent. Although the Declaratory Judgment Act, 28 U.S.C. § 2201, permits parties to file suits in which (as here) the only relief sought is declaratory in nature, it did not (and could not) relax Article III's command that an actual case or controversy exist before federal courts may adjudicate a question. U.S. Const., Art. III, § 2. *See Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 272-73 (1941).[7] The Act merely provides a different procedure for bringing an actual case or controversy before a federal court; it does not purport to expand federal court jurisdiction. *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240 (1941). Review is warranted because the court below established a rule that will result in the Federal Circuit exercising jurisdiction over a broad category of cases in which no actual case or controversy exists.

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[7] The Act provides in relevant part:

> In a case of actual controversy within its jurisdiction . . . any Court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.

28 U.S.C. § 2201(a). As the Court has explained, § 2201(a)'s "actual controversy within its jurisdiction" language refers to the types of "Cases" and "Controversies" that are justiciable under Article III. *MedImmune*, 127 S. Ct. at 771

In *MedImmune*, the Court recently reiterated the traditional formulation regarding the minimum prerequisites necessary to meet the case-or-controversy requirement:

> Basically, the question in each case is whether the facts alleged, under all the circumstances, show th at there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

MedImmune, 127 S. Ct. at 771. Caraco does not meet those prerequisites: there is *no* controversy (and certainly not a "substantial" one) between the parties regarding the '941 patent, they have no adverse legal interests, and any controversy lacks immediacy given the absence of any ongoing relationship between them. Forest reinforced that point by providing Caraco with an unconditional covenant not to sue, thereby eliminating any possible controversy and rendering moot all claims related to the '941 patent.

A. Caraco Lacks Article III Standing

As the Federal Circuit recognized, Pet. App. 23a, an action is not justiciable under Article III where the Plaintiff lacks standing. *Lujan v. Defenders of Wildlife*, 504 U.S. 550, 560 (1992). The "irreducible constitutional minimum" of standing contains three elements: the plaintiff must (1) have suffered a "concrete," "particularized," and "actual or imminent" injury-in-fact that (2) is "fairly traceable to the challenged action of the defendant" and that (3) is likely to be redressed by a favorable decision. *Id.* at 560-61.

In finding that those three elements were met in this case, the Federal Circuit adopted an analytic approach that conflicts sharply with this Court's approach to standing issues.

The appeals court held that Caraco has suffered injury-in-fact directly traceable to Forest's conduct because Forest's decision to supply information to FDA regarding the '941 patent may, through a complex chain of events, delay the date on which Caraco eventually obtains FDA approval of its ANDA. Pet. App. 24a-27a. But the court failed to explain why that alleged injury bears any relation to the claims in this lawsuit – which challenges the '941 patent itself, not the decision to post it in the Orange Book.

As the Court has explained:

> [S]tanding is gauged by the specific common-law, statutory, or constitutional claims that a party presents. "Typically, . . . the standing inquiry requires careful judicial examination of a complaint's allegations to ascertain whether the particular plaintiff is entitled to an adjudication *of the particular claims asserted*."

Primate Protection League v. Administrators of Tulane Educ. Fund, 500 U.S. 72, 77 (1991) (quoting *Allen v. Wright*, 468 U.S. 737, 752 (1984)) (emphasis in original). The particular claim asserted in this case is that Caraco's proposed drug does not infringe the '941 patent; in other words, the lawsuit focuses on the existence and scope of the patent. But the injury alleged by Caraco (and accepted by the Federal Circuit as sufficient to establish standing) has nothing to do with

the existence and scope of the '941 patent. Rather, the Federal Circuit held that Caraco's injury consists of the fact that Forest took steps that resulted in FDA listing the '941 patent in the Orange Book. Because that alleged injury has at most a highly tangential relationship to the existe nce and scope of the '941 patent, it is insufficient to constitute the injury-in-fact necessary to provide Caraco with standing.

The Court's decision in *Blum v. Yaretsky*, 457 U.S. 991 (1982), is illustrative. The plaintiffs in *Blum* represented a class of Medicaid patients who were challenging procedures employed by hospital officials in transferring patients both to higher and lower levels of care. The Court held that although the plaintiffs could demonstrate injury-in-fact with respect to procedures governing transfers to lower levels of care, such injury was insufficient to provide them with the injury-in-fact necessary to establish standing to challenge procedures governing transfers to *higher* levels of care. *Blum*, 457 U.S. at 1001. The Court explained that merely because one action taken by a defendant has injured a plaintiff does not mean that the plaintiff possesses standing to file suit against the defendant for the defendant's other, largely unrelated actions that have not injured the plaintiff. *Id.* at 999. Similarly, by supplying information to FDA regarding the '941 patent (an action required by the FDCA in connection with all new drug applications) and thereby ensuring that the '941 patent would be listed in the Orange Book, Forest arguably injured Caraco by making it marginally more difficult for Caraco to obtain FDA approval of its ANDA. But any such injury is wholly unrelated to this lawsuit, which challenges the scope of the '941 patent, not its listing in the Orange Book. To establish standing to file

this declaratory judgment action, Caraco would need to demonstrate that the existence of the '941 patent was injuring it in some way; Caraco has made no such demonstration.

B. *MedImmune* Provides No Support for the Appeals Court's Standing Determination

The Federal Circuit cited this Court's *MedImmune* decision as its justification for expanding the circuit's prior understanding regarding when a party has standing to file an action seeking a declaratory judgment that a patent is either invalid or not infringed. However, its understanding of *MedImmune* was fundamentally flawed. Prior to *MedImmune*, the Federal Circuit adhered to a "reasonable apprehension of suit" test, pursuant to which the case-or-controversy requirement was held to bar suits by a party seeking a declaratory judgment that a patent was invalid or not infringed, unless the party had a reasonable apprehension that the patent holder would sue him for infringement. *See, e.g., Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1333 (Fed. Cir. 2005). *MedImmune* disapproved of the reasonable apprehension test, finding it inconsistent with Supreme Court precedent and an overly narrow interpretation of the case-or-controversy requirement. *MedImmune*, 127 S. Ct. at 774 n.11. But while *MedImmune* expanded the Federal Circuit's prior understanding of Article III jurisdiction, it did so in a manner wholly unrelated to the facts of this case.

MedImmune addressed a situation in which the party seeking declaratory relief is himself preventing the

complained-of injury from occurring. That is, only by complying with a demand from the defendant, a demand to which he objects, is the declaratory judgment plaintiff forestalling injury. The Supreme Court noted that under well-established case law, where the demand for compliance comes from the *government*, such a plaintiff need not refuse to comply with the demand – thereby exposing himself to government sanction – before being permitted to seek declaratory relief. *Id.* at 772.[8] The Court determined that the same rule should apply where the demand for compliance comes not from the government but from a private party, at least where the threatened sanction for noncompliance is quite severe: "The rule that a plaintiff must destroy a large building, bet the farm, or (as here) risk treble damages and the loss of 80% of its business, before seeking a declaration of its actively contested legal rights finds no support in Article III." *Id.* at 775. Thus, the *MedImmune* plaintiff was permitted to seek a declaratory judgment that it was not infringing a patent at the same time that it was forestalling a potentially devastating infringement action by paying royalties to the patent holder. *Id.* at 777. The issue was no less a "substantial controversy" between the parties simply because the plaintiff was paying tribute to the patent holder under protest. *Id.*

Caraco's situation does not even remotely resemble the facts in *MedImmune*. Caraco is not making any payments to Forest or taking any other

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[8] Thus, in *Steffel v. Thompson*, 415 U.S. 452 (1974), the Court "did not require the plaintiff to proceed to distribute handbills and risk actual prosecution before he could seek a declaratory judgment regarding the constitutionality of a state statute prohibiting such distribution." *Id.*

actions at Forest's behest. Caraco is refraining from marketing a generic form of Lexapro not because of any actions by Forest but because FDA has not approved its ANDA. Nor has Forest ever given Caraco any indication that it intended to sue for infringement of the '941 patents; to the contrary, Forest provided Caraco with an unconditional covenant *not* to sue. Moreover, Caraco is attempting to use a declaratory judgment action for the purpose warned against in *MedImmune*: it is seeking piecemeal adjudication of its claims, with the hope that a judgment here will benefit it in other proceedings. *Id.* at 771 n.7 ("[A] litigant may not use a declaratory-judgment action to obtain piecemeal adjudication of defenses that *would not finally and conclusively resolve* the underlying controversy.") (citing *Calderon v. Ashmus*, 523 U.S. 740 (1998)). In short, despite the Federal Circuit's reliance on *MedImmune*, nothing in that decision provides support for the appeals court's conclusion that Caraco meets the case-or-controversy requirement.

Caraco, as the party claiming declaratory judgment jurisdiction, bears the burden of establishing that such jurisdiction existed at the time it filed suit *and at all times thereafter*. *Steffel,* 415 U.S. at 459 n.10. Even if Caraco arguably possessed standing at the time it filed its complaint, that standing was eliminated once Forest provided its unconditional covenant not to sue – thereby eliminating any possible claim of injury arising by virtue of the '941 patent. From that point forward, any arguable claim possessed by Caraco with respect to the '941 patent was rendered moot. Caraco is asking the federal courts to reach a legal determination that Forest has pledged not to challenge: that Caraco's Paragraph IV certification did not violate Forest's rights under the

'941 patent. The federal courts lack Article III jurisdiction to issue such advisory opinions.

Finally, even if the injury allegedly suffered by Caraco (a potential delay in approval of its ANDA) could be deemed traceable to the mere existence of the '941 patent, that relationship is far too attenuated to establish standing. *Regardless* how this suit is resolved, the most likely date on which Caraco will obtain FDA approval of its ANDA is 180 days following expiration of the '712 patent in 2012. While a judgment for Caraco in this case would prevent that date from being delayed, the Federal Circuit conceded that there is no evidence indicating that such a delay is likely.[9] For Caraco to obtain FDA approval of its ANDA prior to 2012, it will need to prevail in court on its claim that the '712 patent is invalid – and there is no basis for assuming it "likely" that Caraco will prevail given that Ivax's identical effort to overturn the '712 was unsuccessful. Accordingly, Caraco cannot meet the "redressability" requirement for standing, because it cannot establish that it is "likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Lujan*, 504 U.S. at 561. While Caraco *might* be helped by a favorable decision in this case, it is just as likely that a favorable decision will have *no* effect on the date on which Caraco's ANDA ultimately receives FDA approval.

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[9] A decision by Ivax to delay marketing even after expiration of the '712 patent in 2012 could delay the triggering of Ivax's 180-day exclusivity period. But a judgment for Caraco in this case with respect to the '941 patent combined with the expiration of the '712 patent would ensure that Ivax's exclusivity period would expire after the elapse of 180 days following the patent's expiration in 2012.

II. THE DECISION BELOW SUBSTANTIALLY REVISES THE BALANCE STRUCK BY CONGRESS AND AFFECTS A SUBSTANTIAL NUMBER OF CASES

Review is also warranted because the decision below will likely have a substantial impact on pharmaceutical innovation. Petitioner has explained that impact in significant detail, Pet. 31-35; rather than repeating that explanation fully here, WLF will focus on a few major points.

First, as noted above at 3-4, the Hatch-Waxman Act was intended to establish a careful balance between rewarding innovation (by providing market exclusivity to those who develop new therapies) and reducing consumer costs (by encouraging competition after an appropriate period of exclusivity has expired). By abandoning traditional standing rules in an effort to encourage more competition at any earlier stage of product development, the Federal Circuit is threatening to upset that balance. Review is warranted to ensure that any changes in the Hatch-Waxman balance are effected by Congress, not the courts.

Second, the Federal Circuit's re-writing of the Hatch-Waxman compromise harms not only pioneering drug companies but also generic drug companies who assume the substantial costs of being the first to challenge a drug patent by filing the first Paragraph IV certification with respect to the patent. Congress created the 180-day exclusivity period for first filers to encourage generic drug companies to assume the costs of challenging patents of dubious validity. Review is warranted because the decision below undermines those

intended financial incentives by allowing suits, as here, whose principal purpose is to limit or destroy a first-filer's 180-day exclusivity period.

Third, as the Petition indicates, the questions presented herein are present in scores of pending drug patent cases and thus are of tremendous importance to the pharmaceutical industry and our Nation's health care delivery system. Moreover, the 2003 changes to the law are unlikely to decrease the frequency with which the issue arises in the future. The MMA revised the law by eliminating the court-judgment trigger provisions of 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000). But as the Federal Circuit noted, its jurisdictional analysis is as applicable to the new law as it is to the pre-2003 law. Pet. App. 10a n.4.[10] In both instances, the decision below would grant standing to a generic drug manufacturer who filed an action seeking a declaratory judgment that its Paragraph IV certification did not infringe a patent listed in the Orange Book – regardless whether the patentee had ever suggested that it might bring an infringement action. Under the decision below, standing would exist so long as it is *possible* that a judgment for the plaintiff could speed the approval of the plaintiff's ANDA – a possibility that will always exist under both the old and new statutory schemes. Accordingly, review is warranted in light of the large number of cases that are affected and will continue to be

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[10] Under the law as revised by the MMA, a judgment finding that a drug patent is either invalid or not infringed by a Paragraph IV certification effectively requires the first filer to begin marketing immediately. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb). That provision serves the same function as § 355(j)(5)(B)(iv)(II) (2000), the court-judgment trigger provision of the pre-2003 statute.

affected by the decision below.

CONCLUSION

Amicus curiae Washington Legal Foundation respectfully requests that the Court grant the petition for a writ of certiorari.

Respectfully submitted,

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Dated: December 10, 2008